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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/143,143 08/28/98 ASH

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EXAMINER

PAK, J

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/143,143

Applicant(s)
ASH

Examiner
John Pak

Group Art Unit
1616



☒ Responsive to communication(s) filed on Nov 21, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 24-29, 31-37, 39-41, 44, and 46-66 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 24-29, 31-37, 39-41, 44, and 46-66 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 14

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claims 24-29, 31-37, 39-41, 44 and 46-66 are pending in this application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-29, 31-37, 39-41, 44 and 46-66 are rejected under 35 USC 103(a) as being unpatentable over the combined teachings of Harber et al. (GB 2,177,021) and Bellini et al. (EP 612,528) in view of the acknowledged prior art and Martindale The Extra Pharmacopoeia (hereinafter, Martindale).

Discussion of teachings and reliance of Bellini et al., the acknowledged prior art, and Martindale have been set forth in the previous Office Action, Paper No. 11 (5/18/00), pages 3-5 and **incorporated by reference** herein with the **exception** of applicant's admission discussed in line 7 of page 4 of Paper No. 11, in view of the claim of domestic priority made by applicant in his reply of 11/21/00.

The only new reference applied here is Harber et al., submitted by applicant in his reply of 11/21/00.

Harber et al. disclose the use of a "non-toxic iron-chelation substance" (claim 1) such as "non-protein iron-chelator" (page 1, lines 35-39) in peritoneal dialysate solutions

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to prevent peritonitis (page 1, lines 1-42). Concentration of the iron chelator is from 5 to 50 uM, which is approximately 27.9 to 279 ug/dl iron (page 1, lines 37-39). Ferric chloride is disclosed as one specific example of a non-protein iron-chelator, and its exemplified concentration is 10 uM, which is approximately 57.8 ug/dl iron (page 1, lines 45-51). Use of the iron-chelator in peritoneal dialysis fluid, which contains "various salts, glucose and lactate" is disclosed See page 1, lines 71-76 and claims 1-6.

While the prior art does not explicitly disclose iron complex of the instant invention with the specific 223-323 mEq/L electrolyte concentration in the dialysate and with specific intended use disclosure of the iron compounds for delivery of iron, it is the Examiner's position that the claimed invention would nonetheless have been prima facie obvious to the ordinary skilled artisan at the time the invention was made.

A person having ordinary level of skill in the highly specialized art of providing peritoneal dialysis would have known what level of mEq/L of electrolytes are needed depending on patient profile. As for iron delivery, both Harber et al. and Bellini et al. teach dialysate formulations that contain iron compounds that are readable on the instant invention. While applicant argues in his ~~11~~/21/00 response that Bellini et al. do not in fact disclose ferric gluconate in their peritoneal dialysate solution because only a "laundry list" of gluconate osmotic substances are disclosed, one of them being ferric gluconate, the Examiner wishes to point out that the alleged "laundry list" is quite an exaggeration since only six specific gluconates are exemplified by Bellini et al. Further,

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Harber et al. combine to suggest to the ordinary skilled artisan that the use of ferric gluconate would have multiple functionalities and advantages as a component of a peritoneal dialysis solution.

One having ordinary skill in the art would recognize that the iron compounds disclosed and suggested in the prior art dialysate formulations would function to deliver iron, while providing other concomitant functions; and given the well known fact that chronic dialysis patients often require iron supplementation, the ordinary skilled artisan would have been motivated to utilize the iron compound containing dialysis fluids of the prior art to treat dialysis patients who are in need of iron supplementation. New claims directed to concentrated forms of the dialysate solution are noted, but it is held to be well within the skill of the ordinary skilled artisan in this field to dilute concentrated forms to arrive at the desired target concentration of ingredients (see e.g. Bellini et al., page 4, lines 44-46).

For these reasons and the reasons of record, the claims are rejected again.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

